THE CENTRAL AFRICAN JOURNAL OF MEDICINE

Vol. 50, Nos. 11/12 November-December 2004

CONTENTS

THE CENTRAL AFRICAN JOURNAL OF MEDICINE

ORIGINAL ARTICLES

Adverse drug reactions reporting at a referral hospital in Zimbabwe

*S KHOZA, *I MADUNGWE, **P NYAMBAYO, *J MTHETHWA *O CHIKUNI

Abstract

Objectives: To establish factors influencing voluntary reporting of adverse drug reactions among health workers. A second objective was to establish the level of awareness on adverse drug reaction reporting and attitudes towards the voluntary adverse drug reaction reporting scheme.
Design: Cross sectional descriptive study.
Setting: Parirenyatwa Hospital, a major referral and teaching hospital in Harare, Zimbabwe.
Subjects: 200 health professionals randomly selected from various departments.
Main Outcome Measures: Number of health workers reporting adverse drug reactions; awareness of the adverse drug reaction reporting scheme.
Results: 144 (72%) questionnaires were completed. About half (47.2%) of the respondents did not know how to report an adverse drug reaction and 47.1% were unaware of the existence of a formal adverse drug reaction reporting scheme in Zimbabwe. One fifth (20.1%) of the respondents had reported an adverse drug reaction at some point. Two main factors contributing to under-reporting cited by respondents were the poor feedback from the national reporting centre (59%) and inaccessibility of reporting facilities (45.8%). Beliefs that one should only report an adverse drug reaction if certain of causality (46.5%) and that really serious adverse drug reactions are well documented before a drug is marketed (35.4%) could also account for under reporting. However, 75.7%, viewed adverse drug reaction reporting as a professional obligation.
Conclusion: Lack of awareness of healthcare professionals to the national (Medicines Control Authority of Zimbabwe) adverse drug reaction voluntary reporting scheme, poor feedback and inaccessibility of reporting facilities are the main factors contributing towards underreporting.

Cent Afr J Med 2004;50(11/12):104-7

Introduction

Adverse drug reactions (ADRs) are fairly common and are responsible for a significant number of hospital admissions with reported ranges of 0.3-7%.[1] Studies have also shown that ADRs are very costly.[2] The outcome of an ADR can be serious and result in illness, injury or even death. Early recognition of a drug's potential adverse reaction profile is, therefore, critical in ensuring safety for the user of drugs, as well as reducing costs attributable to ADRs. An attempt is made during pre-marketing trials to identify the adverse reaction profile of the drug, but these trials do not

*Department of Clinical Pharmacology
University of Zimbabwe
Medical School
P O Box A178, Avondale
Harare, Zimbabwe
**Medicines Control Authority of Zimbabwe
109 Baines Avenue
Harare, Zimbabwe

Correspondence and reprint requests to:
S Khoza
*Department of Clinical Pharmacology
University of Zimbabwe
Medical School
P O Box A178
Avondale, Harare

quite effectively identify all ADRs mainly due to the relatively small number of patients evaluated. Clinical trials are usually of short duration and hence are not adequate to detect delayed consequences associated with long term drug administration. These trials also exclude special groups such as pregnant women, children, the very old and patients with multiple disease states or any other complicating factors, who may be at higher risk for unique ADRs compared to the general population.[3] ADRs due to drug interactions are difficult to detect in pre-marketing studies.[4]

The limitation of pre-marketing trials means that approval of a new drug does not exclude the possibility of rare but serious ADRs or common delayed ADRs. Continuous post-marketing monitoring and reporting of ADRs is, therefore, necessary. Voluntary reporting of ADRs is almost certainly the most cost effective and practical way of gathering post-marketing drug safety information continuously. Some studies have suggested the voluntary reporting system may be the only affordable mechanism available for early detection of serious clinical events that occur less frequently than once per 10 000 drug exposures.[5]

Accumulating evidence suggests that healthcare workers' attitudes towards their national ADR reporting schemes are significant determinants of reporting rates. Therefore insights into the reasons for under reporting might enable the national reporting centre, Medicines Control Authority of Zimbabwe (MCAZ) to take appropriate measures to increase reporting rates, hence the need to investigate factors influencing ADR reporting.

Voluntary ADR reporting schemes have operated since the 1960s in many western countries. These surveillance systems enable healthcare workers to report suspected ADRs and thus act as a tool to identify new ADRs and risk factors predisposing to recognised ADRs. However, under reporting has been shown to be the major weakness of the system and a small proportion of ADRs are actually reported to national reporting centres. Professionals in the field of pharmacovigilance agree that international ADR reporting rates, even of serious reactions are very low.[6]

In Zimbabwe there has been a very slow response from health workers in reporting ADRs. Improvement of reporting rates is thus a major priority of the national reporting centre.

Materials and Methods

The study was carried out at Parirenyatwa Hospital, a teaching hospital in Harare during the period February to March 2004. Healthcare professionals from internal medicine, paediatrics, the intensive care unit, outpatients, casualty, obstetrics, ophthalmology, dentistry, pharmacy and rehabilitation departments were interviewed and these included: nurses, doctors, dentists, pharmacists, physiotherapists and pharmacy technicians.

Participating doctors and nurses were systematically selected from the lists obtained from the staffing department (every third nurse and every second doctor on the respective lists). However, because of the small number of staff in the other professions in the hospital, all were targeted.

A self-administered questionnaire was distributed to 200 targeted participants: 100 nurses, 50 doctors, 18 dentists, 15 physiotherapists, 14 pharmacists and three pharmacy technicians. The questionnaire was distributed to the participants in their respective departments and collected within a period of two weeks, after which the participants were considered as non-responders. The questionnaire was adapted from that used in other studies [6] and modified after a pilot study. Demographic data, awareness of the MCAZ's voluntary reporting scheme, knowledge about the operation and purpose of the reporting scheme as well as attitudes towards ADR reporting was collected. Knowledge and attitudes were measured using a series of statements, to which the respondent was to indicate if he/she agreed, did not agree or was not sure.

Results

One hundred and forty four (72%) participants completed and returned the questionnaire, of which 57.6% (83) were females, and 51.4% (74) were nurses, 24.3% (35) doctors, 6.9% (10) dentists, 6.3% (nine) physiotherapists, 9% (13) pharmacists and 2.1% (three) pharmacy technicians. The sample consisted of participants mainly below the age of 30 years (71%) and those between 30 to 40 years (26%). Those above 40 years constituted 3% of the respondents. Of the respondents 75% had less than five years of post-training working experience, 19.4% had between five to 10 years whilst 5.6% had over 15 years of service.

Figure I: Awareness of Medicines Control Authority of Zimbabwe Adverse drug reaction reporting scheme.

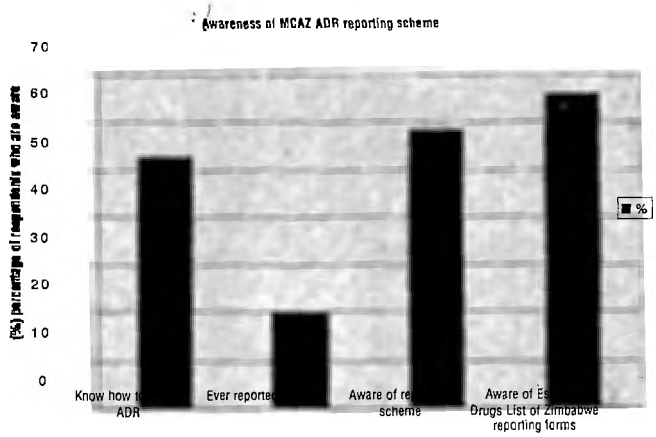

Figure I above shows that 58.3% of the respondents knew that a formal ADR reporting scheme exists while 52.8% knew how to report an ADR and 66% knew about ADR forms in the Essential Drugs List of Zimbabwe (EDLIZ). Out of all the respondents only 20.1% had

reported an ADR to the MCAZ even though all indicated that it was important to do so. Of those who had reported an ADR, 69% were females and 65.5% were nurses, while 21% were doctors. However, there was no significant difference in the reporting rates between nurses and other professionals (p = 0.0883).

Table I: Knowledge on purpose of ADR reporting.

Question	Response (%) Agree	Not Sure	Disagree
Purpose of ADR reporting scheme			
Enable safe drugs to be used	82.6	16	1.4
Measure incidence of all ADRs	77.1	16	6.9
Identify factors predisposing to ADRs	72.9	22.9	4.2
Identify previously unregonised ADRs	84	13.9	2.1
Compare brand and generic products	38.9	48.6	12.5
To obtain information about characteristics of certain ADRs	83.3	14.6	2.1
To compare ADRs in Zimbabwe to those experienced elsewhere	50.7	38.2	11.1
Potential for improving quality of care	97.9	1.4	0.7

Most of the respondents were able to correctly identify the purposes of having a reporting scheme as shown in Table I. However, only 38.9% knew that such a system could be used to compare brand and generic products and some did not realise it could be used to compare ADRs in Zimbabwe to those experienced elsewhere.

Table II: Attitudes towards ADR reporting.

Attitude or opinion	Response (%) Agree	Neutral	Disagree
Really serious ADRs are well documented before a drug is marketed	35.4	31.9	32.6
It is really impossible to determine if a drug is responsible for a particular ADR	18.1	36.8	45.1
I would only report an ADR if I am sure that it is related to the use of a particular drug	46.5	9.7	43.8
The one case a physician might see cannot contribute to medical knowledge cannot	10.4	29.2	60.4
I should be financially reimbursed or providing service of ADR reporting	9	9	81.9
I have a professional obligation to reporting ADRs	75.5	14.6	9.7
Reporting ADRs risks my career	5.6	11.1	83.3
It is only necessary to report serious ADRs	17.4	13.9	68.8
It takes too much time to report ADRs	16	43.8	40.3
May look foolish in reporting suspected ADRs	9.7	11.1	79.2
Lack of, or slow feedback from national reporting centre discourages reporting	59	31.9	9
Some ADRs are too trivial to be reported	30.6	29.9	39.6
Some ADRs are too well known to be reported	16.7	14.6	68.8
Reporting facilities not readily accessible	45.8	39.6	14.6

It appears the slow feedback from the national reporting centre and unavailability of reporting facilities are two of the major factors that could be contributing to the low reporting rate.

Discussion

The lack of awareness (41.7%) on MCAZ's voluntary reporting and the fact that about half (47.2%) of the respondents did not know how to report an ADR may mean that quite a significant number of ADRs worth reporting go unreported. This low level of awareness could mean that the MCAZ ADR reporting scheme is not well published. Several studies have reported improved reporting of ADRs following awareness campaigns and education on the importance of reporting.[7,8] Therefore continuous education, explaining reporting procedures to new members of staff and emphasising the importance of reporting may improve the reporting of ADRs.

The quality of the relationship between the individual and the national reporting centre is a strong motivating factor. In one study, those who were given feedback or whose efforts were positively appreciated and who were helped to understand the part their contribution played in the national drug safety programme, expressed a commitment to ADR reporting, while those that felt distanced from the national programme and had no evidence of positive use of their reports showed less commitment in future.[9]

Other studies have also reported similar results to those presented in this study, for example, the lack of, or slow feedback from the national reporting centre has been found to discourage reporting.

Inaccessibility of reporting facilities and lack of means of reporting also hamper the process of ADR monitoring. Reporting forms should always be accessible in all departments in a health institution and must be postage paid to facilitate reporting. Increased accessibility of these reporting facilities resulted in an increase in ADR reporting in the Rhode Island ADRs Reporting Project.[7]

When reporting an ADR, a health worker is not required to be certain of causality. Suspecting a drug in an observed ADR is sufficient to make a report to the national reporting centre. One of the reasons for not reporting an adverse event is when it is too trivial. This is a valid reason as it spares the voluntary reporting system, because reporting all side effects and nuisance symptoms will overburden the system and hamper it in efficiently responding to signals of serious risk.

The belief among some respondents that some ADRs are too well known to be reported may result in underestimating the prevalence of some adverse events in the population. If an intolerable adverse event occurs in more than 20% of patients and there are other safer drugs, it may be worth considering alternatives in place of the drug in question. However, this decision to protect the patients from such an adverse event can only be made if the monitoring centre has sufficient data. As such, reporting of even common ADRs is very important for the quality care of patients.

The good attitude among respondents that it is their professional responsibility (75%) to report ADRs will go a long way in protecting patients from serious adverse events if the reporting scheme is publicised well.

The sample consisted of more females of which most were nurses. Nurses are in continuous contact with hospitalised patients and hence have more chances of detecting adverse events and making a report. This study observed that nurses were more likely to make an ADR report than other health care workers.

The study underscores the need to raise the profile of pharmacovigilance and create a reporting culture in health workers in Zimbabwe. The reporting system should be widely publicised and if possible have an ADR bulletin that will be circulated to all health institutions. The national reporting centre should positively encourage and appreciate voluntary reporting and provide feedback through the ADR bulletin or newsletter.

Conclusion

Lack of awareness and knowledge on the operation of the MCAZ's voluntary reporting system is a major contributing factor in under-reporting of ADRs. This is further compounded by the poor feedback from the reporting centre and the unavailability of readily accessible reporting facilities. Publicising the reporting scheme is likely to improve ADR reporting in Zimbabwe.

References

1. May RJ. Adverse drug reactions and interactions. In: Dipiro J.T, Talbert R.L, Yee G.C, *et al.* Pharmacotherapy. A pathophysiologic approach. 3rd ed. Appleton & Lange; 1997;106-16.
2. Bates DW, Leape LL, Cullen DJ, *et al.* Incidence of adverse drug events and potential adverse events and potential adverse drug events: Implications for prevention. *JAMA* 1995;274: 29-34.
3. Brewer T, Colditz GA. Postmarketing surveillance and ADRs, current perspectives and future needs. *JAMA* 1999;281(9):824-9.
4. Peck CC, Temple CR, Collins JM. Understanding consequences of concurrent therapy. *JAMA* 1993;269:1550-52.
5. Rossi AC, Knapp DE, Annelo C. Discovery of ADRs: a comparison of selected phase 4 studies with spontaneous reporting methods. *JAMA* 1983; 249:2226-8.
6. Rogers AS, Israel E, Smith CR, Physician knowledge, attitudes and behaviour related to reporting adverse drug events. *Arch of Int Med* 1988; 48:1596-600.
7. Scott HD, Thather-Renshaw A, Rosenbaum SE. Physician reporting of ADRs: results of the Rhode Island ADRs Reporting Project. *JAMA* 1990; 263:1785-8.
8. Clarkson A, Ingleby E, Choonora I, *et al.* A novel scheme for reporting ADRs. *Arch of Dis Childhood* 2001; 84:337-9.
9. Biriell C, Edwards IR. Reasons for reporting ADRs: some thoughts based on international review. *Pharmacoepidemiology and Drug Safety* 1997; 6:21-6.